REMARKS

Reconsideration and allowance of the above-identified application are respectfully requested. Upon entry of this Amendment, claims 1-69 will be pending.

The Examiner has made a minor objection to the specification with regard to the subject matter recited in claims 11 and 35. Also, claims 11 and 35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. It is believed that the above amendments to claims 11 and 35 overcome the objection and rejection.

Claims 48 and 64 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. It is believed that the above amendments to paragraph 0037 of the specification, which incorporate the limitations of these claims into the appropriate portion of the detailed description of the application, overcome this rejection without adding any new matter. The Examiner is therefore respectfully requested to withdraw this rejection.

Applicants appreciate the Examiner's indication that claims 20, 21, 41 and 42 define allowable subject matter. Accordingly, dependent claims 20 and 41 are written in independent form as claims 66 and 68, respectively, and claims 21 and 42, which depend from claims 20 and 41, respectively, are copied as new claims 67 and 69 which depend from claims 66 and 68, respectively. It is believed that these claims are in condition for allowance.

Turning now to the art-based rejections, claims 1, 2, 9, 10, 13-19, 22-26, 33, 34, 37-40, 43-47, 49, 56, 57, 59-63 and 65 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,275,717 to Gross et al. Furthermore, claims 1, 7, 11-14, 16, 18, 24, 25, 31, 35-38 and 40 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,501,976 to Sohrab. In addition, claims 1, 7, 13, 14, 16, 18, 19, 24, 25, 31, 37, 39 and

40 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,104,940 to Watanabe et al. Also, claims 3-5, 27-29 and 50-52 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gross et al. patent in view of U.S. Patent No. 5,527,334 to Kanner et al. Additionally, claims 6, 30 and 53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gross et al. patent in view of U.S. Patent No. 6,136,008 to Becker et al., and claims 8, 32 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gross et al. patent in view of U.S. Patent No. 6,558,320 to Causey, III et al. Furthermore, claims 8, 32 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sohrab and Causey et al. patents, and claims 9, 22, 23, 33, 43-47, 49, 54, 57, 58, 60-63 and 65 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sohrab patent in view of the Gross et al. patent. Finally, claims 12, 36 and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gross et al. and Sohrab patents.

As discussed in more detail below, Applicants respectfully submit that none of these references, viewed individually or in combination, teach or suggest a minimally-invasive analyte detecting device or method employing an active electrode and a counter-electrode, where the active electrode has a length that is limited to enter the stratum corneum of a patient *to a depth less than a depth in a dermis in which nerve endings reside.*

An embodiment of the present invention provides a device for detecting at least one analyte in a patient. The device comprises at lest one active electrode and at least one auxiliary electrode configured to at least partially surround the active electrode. As described, for example, in paragraph 0032 and in the Abstract of the present application, the active electrode has a length that enables it to pass through the stratum corneum to a depth sufficient

to access the analyte but less than a depth in the dermis at which nerve endings reside. Hence, the active electrode, in conjunction with the auxiliary electrode that contacts the patient's skin when the device is placed against the patient, operate to electro-mechanically detect the analyte.

These features are recited in amended independent apparatus claims 1 and 24 and in independent method claims 45 and 61. As discussed above, none of the cited references teaches or suggests these features.

The rejections will now be addressed individually.

The § 102(e) Rejection Based on the Gross et al. Patent.

The Examiner relies on the Gross et al. patent as allegedly teaching a detection device and method capable of detecting an analyte in a patient in a manner similar to that of the claimed embodiments. In particular, the Examiner contends that the Gross et al. patent teaches a device which includes an active electrode 15 and an auxiliary electrode 16 or 17 as shown in Figs. 1a and 2. The Examiner contends that these features therefore meet the limitations pertaining to the "active electrode" and "auxiliary electrode" as recited in independent claims 1, 24, 45 and 61. However, Applicants note that as indicated above, these claims were amended to clarify that the length of the active electrode is limited so that when the device is placed against the patient's skin, the active electrode penetrates to a depth which does not contact the nerve endings in a patient. As described, for example, in paragraph 0032 of the present application, in order to achieve this, the length of the active electrode can be within the range of, for example, 100-2000μm. On the contrary, as described in column 10,

lines 54-59 of the Gross et al. patent, the needle 15 has a length of 5 mm. Applicants respectfully submit that this length would result in the needle penetrating the nerve area in the dermis of the patient, thus causing the patient much discomfort. In other words, it would not be reasonable to construe the needle 15 as taught by Gross et al. patent to be a minimally invasive needle.

Applicants also recognize that column 10, lines 58-59 of the Gross et al. patent generally state that a "wide variety of dimensions can be employed as required". However, Applicants submit that nowhere does the Gross et al. patent teach or suggest that such dimensions should be limited by the concern of avoiding contact with the nerve endings in the dermis. Applicants therefore submit that the Examiner would need to use knowledge of the invention, in hindsight, to construe this phrase as limiting the length of the needle to avoid contact with the nerves. However, it is well settled that such a "hindsight reconstruction" is prohibited. Accordingly, Applicants submit that teachings of the Gross et al. patent do not anticipate even the amended independent claims. Therefore, all claims should be allowable over the Gross et al. patent.

The § 102(e) Rejection Based on the Sohrab Patent.

In this rejection, the Examiner contends that the first electrode 108 of the micro-needle 100 taught by Sohrab corresponds to the "active electrode", while the second electrode 112 corresponds to the "auxiliary electrode". Applicants note, however, that the Sohrab patent teaches a micro-needle 100 including an electrochemical cell that comprises the first electrode 108 and the second electrode 112. Unlike the claimed embodiments of the present

invention in which the first electrode penetrates to a certain defined depth in the dermis, in the Sohrab device, the micro-needle 100 penetrates the skin and a biological fluid sample enters the lumen 120 of the micro-needle 100 by capillary action. The fluid can then contact the first electrode and second electrode. In other words, the micro-needle 100 captures a fluid sample that is analyzed by the electrochemical cell including the first and second electrodes.

Because the construction and operation of Sohrab device is completely unlike that of claimed embodiments of the invention as recited even in the amended independent claims, all claims should be allowable over the Sohrab patent.

The § 102(e) Rejection Based on the Watanabe et al. Patent.

In this rejection, the Examiner contends that the probe one taught by Watnabe includes a working electro lead 3 that corresponds to the "active electrode" and a counter electrode 4 that corresponds to the "auxiliary electrode" as recited in the claims. Applicants respectfully submit, however, that, nowhere does the Watanabe patent teach or suggest the limitations in the length of the active electrode as recited in the amended independent claims. For example, column 3, line 36-37 teach that the needle member 2, which includes the working electrode 3 and counter electrode 4, is 50 mm in length and 2 mm in diameter. These dimensions are completely unlike those of the claimed embodiments of the present invention that specifically limit the depth to which the active electrode can penetrate the patient in order to avoid contact with the nerve endings. Furthermore, in the probe 1, both the working electrode 3 and counter electrode 4 enter the patient, as opposed to the "auxiliary electrode" of the present claimed embodiments which contact the surface of the patient's skin

when the device is placed against the patient and operated to perform the detection. For these reasons, all claims should be allowable over the teachings of the Watanabe patent.

The § 103(a) Rejection Based on the Gross et al. and Kanner et al. Patents.

In this rejection, the Examiner cites the Kanner patent as teaching a retractable needle and contends that it would have been obvious to one skilled in the art to modify the apparatus taught by the Gross et al. patent to achieve the present invention as recited in these claims. Applicant respectfully disagrees. In particular, Applicants respectfully submit that the teachings of the Kanner et al. patent fail to make up for any deficiencies in the teaching of the Gross et al. patent as discussed above with regard to the limited length of the active electrode to avoid contact with the nerve endings of the patient. Furthermore, the Kanner et al. patent merely teaches a single retractable lancet, as opposed to an electrode 15 that is used in conjunction with other electrodes 16 and 17. Therefore, Applicants respectfully submit that one skilled in the art would not have been motivated to modify the teachings of the Gross et al. patent in accordance with teachings of the Kanner et al. patent. However, even if such motivation were to have existed, due to the deficiencies in the teachings of both patents, the combined device would not achieve the embodiments of the present invention even as recited in the independent claims. Hence, all claims should be allowable over these patents.

The § 103(a) Rejection Based on the Gross et al. and Becker et al. Patents.

In this rejection, the Examiner admits that the Gross et al. patent does not teach an auxiliary electrode having an abrasive surface. However, for this feature the Examiner relies

on the teachings of the Becker et al. patent and contends that one skilled in the art would have found it obvious to modify the electrodes 16 and 17 of the Gross et al. device in accordance with the teachings of the Becker et al. patent to achieve the present invention as recited in claims 6, 30 and 53. Applicants respectfully note, however, that the teachings of the Becker et al. patent do not make up for the deficiencies in the teachings of the Gross et al. patent with regard to the limitation of the length of the active electrode. Hence, Applicants respectfully submit that even if such a modification were to have occurred, the embodiments of the present invention even as recited in the amended independent claims would not have been achieved. Accordingly, all claims should be allowable over this combination of references.

The § 103(a) Rejection Based on the Gross et al. and Causey, III et al. Patents.

In this rejection, the Examiner admits that the Gross et al. patent does not teach a data storage for storing glucose levels. However, for this feature, the Examiner relies on the teachings of the Causey, III et al. patent and contends that one skilled in the art would have found it obvious to modify the Gross et al. device in accordance with these teachings to achieve the present invention as recited in claims 8, 32 and 55. Applicants respectfully disagree.

In particular, Applicants respectfully submit that the teachings of the Causey, III et al. patent do not make up for the deficiencies in the teachings of the Gross et al. patent with regard to the length of the active electrode. Hence, the combined teachings of these patents would not achieve the present invention as defined even in the amended independent claims. Accordingly, all claims should be allowable over these patents.

The § 103(a) Rejection Based on the Sohrab and Causey, III et al. Patents.

In this rejection, the Examiner admits that the Sohrab patent does not teach or suggest the date of storage device. However, as for this feature, the Examiner relies on the teachings of the Causey, III et al. patent. However, as discussed above with regard to the rejection of claims 8, 32 and 55 based on the teachings of the Gross et al. and Causey, III et al. patents, the teachings of the Causey, III et al. patent does not make up for the deficiencies in the teachings of the Sohrab patent with regard to the length of the active electrode as recited in the amended independent claims. Hence, all patent claims should be allowable over these patents.

The § 103(a) Rejection Based on the Sohrab and Gross et al. Patents.

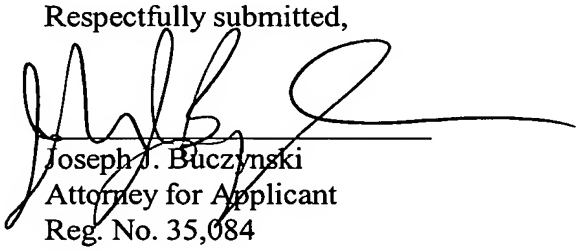
In this rejection, the Examiner admits that the Sohrab patent that does not have a device to communicate with the external equipment as recited in these claims. However, for this feature, the Examiner relies on the teachings of the Gross et al. patent and contends that one skilled in the art would have found it obvious to modify the Sohrab device to include those features to achieve the invention as recited in the rejected claims. Applicants respectfully note that as discussed above, neither of these patents teaches or suggest the limitations on the length of the active electrode as recited in the amended independent claims. Hence, all claims should be allowable over these patents individually or in combination.

The § 103(a) Rejection Based on the Gross et al. and Sohrab Patents.

In this rejection, the Examiner admits the Gross et al. patent that discloses only a single active electrode. However, the Examiner contends that the Sohrab patent teaches the use of multiple active electrodes and contends that one skilled in the art would have found it obvious to modify the Gross et al. patent to include multiple active electrodes to thus meet the present invention as defined in dependent claims 12, 36 and 58. However, as discussed above, neither the Gross et al. nor the Sohrab patent teach or suggest the limitation of the length of the active electrode as recited in the independent claims. Hence, Applicants respectfully submit that all claims should be allowable over these patents when viewed individually or in combination.

In view of the above, it is believed that the subject application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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